Proposed Device Study

- Approved Device used within approved labeling
  - IDE not needed
    - 21 CFR812.(c)(1)(2)
  - IDE not needed
    - 21 CFR812.(c)(3)
  - If PI stated NSR
    - The IRB will review for concurrence

- FDA approved Device used outside approved labeling
  - Study meets exemption criteria?
    - 21 CFR812.2(c)(3)
  - Significant Risk Device?
    - 21 CFR812.3.(m)

- Unapproved Device
  - **IDE required**

For FDA response

- 30-day window
  - Prepare and submit IDE to FDA
    - 21 CFR812.20
  - Respond to FDA questions
    - IDE Approved
      - YES
        - Study may begin
  - IDE not Approved
    - NO
      - Delay or Clinical Hold

Consult FDA as needed:
800-638-2041
Email: DICE@fda.hhs.gov